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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/088,088	03/21/2002	Kiyotaka Ito	220171USOPCT	7118

22850 7590 05/27/2003

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1940 DUKE STREET
ALEXANDRIA, VA 22314

EXAMINER

HABTE, KAHSAY

ART UNIT	PAPER NUMBER
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1624

DATE MAILED: 05/27/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/088,088

Applicant(s)

ITO ET AL.

Examiner

Kahsay Habte, Ph. D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 and 2 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1 and 2 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 3.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: .

DETAILED ACTION

Restriction/Election

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-2 (in part), drawn to compounds where R^1 in formula (I) is pyrazinyl, classified in class 544, subclass various.
- II. Claims 1-2 (in part), drawn to compounds where R^1 in formula (I) is pyrimidinyl, classified in class 544, subclass various.
- III. Claims 1-2 (in part), drawn to compounds where R^1 in formula (I) is pyridizaniyl, classified in class 544, subclass various.
- IV. Claims 1-2 (in part), drawn to compounds where R^1 in formula (I) is pyridyl, classified in class 546, subclass various.
- V. Claims 1-2 (in part), drawn to compounds where R^1 in formula (I) is triazolyl, classified in class 548, subclasses 255, and 262.2.
- VI. Claims 1-2 (in part), drawn to compounds where R^1 in formula (I) is imidazolyl, classified in class 548, subclasses 312.1, 314.7, 315.1; and 338.1.

The inventions are distinct, each from the other because of the following reasons:
Groups I-VI are directed to structurally dissimilar compounds such that the variable core created by the varying definitions of R^1 in formula (I) do not belong to the same recognized class of chemical compounds in the art, and references anticipating one invention, would not render obvious the others. For example, Group I is drawn to

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pyrazines (6-membered ring with 2 nitrogens at 1,4-position) and is different from Groups II-VI. Group II is different from Group I and Groups II-VI, since it is drawn to pyrimidines (6-membered ring with 2 nitrogens at 1,3-position). Group III is different from Groups I-II and Groups IV-VI, since it is drawn to pyridazines (6-membered ring with 2 nitrogens at 1,2-position). Group IV is drawn to pyridines (6-membered ring with one nitrogen) and is different from Groups I-III and Groups V-VI. Group V is drawn to triazoles (5-membered ring with 3 nitrogens) and is different from Groups I-IV and Group VI. Group VI is different from Groups I-V, since imidazoles (5-membered ring with 2 nitrogens at 1,3-position) is not present in other groups. Thus, separate searches in the literature as well as in the U.S. Patent Classification System would be required. Each group's compounds are made and used independently of each other and could support separate patents. The compounds differ significantly in chemical structures. One skilled in the art would not consider such diverse structure equivalents of each other.

During a telephone conversation with Mr. Corwin Umbach on May 20, 2003 a provisional election was made with traverse to prosecute the invention of Group VI, claims 1-2. Affirmation of this election must be made by applicant in replying to this Office action.

Abstract

2. This application does not contain an abstract of the disclosure as required by 37 CFR 1.72(b). An abstract on a separate sheet is required.

3. The claims are drawn to multiple inventions for reasons set forth in the restriction requirement. The claims are examined only to the extent that they read on the elected invention. Cancellation of the non-elected subject matter is recommended in response to this Office Action.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-2 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention:

a. In claim 1, the phrase "An amide compound" is not clear. There is no way of knowing whether applicants intend just carboxylic acid amides, or whether sulfonic, phosphonic, etc amides are intended. It is recommended that applicants amend the claim so that it reads "A compound."

b. In claim 1(line 28), the phrase "and its salt" should read as "or its pharmaceutical salts thereof."

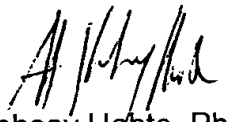
c. In claim 2, the pharmaceutical composition has no pharmaceutical carrier.

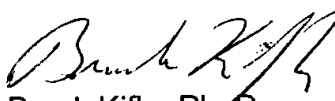
Conclusion

5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kahsay Habte, Ph. D. whose telephone number is (703) 308-4717. The examiner can normally be reached on M-F (9.00AM- 5:30PM).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mukund Shah can be reached on 703-308-4716. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.


Kahsay Habte, Ph. D.
Examiner
Art Unit 1624


Bruck Kifle, Ph. D.
Primary Examiner
Art Unit 1624

KH
May 22, 2003